EFFECT OF INTEGRATED YOGA - SIDDHA MODULE IN THE MANAGEMENT OF TYPE 2 DIABETES MELLITUS

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Abstract

Title: EFFECT OF INTEGRATED YOGA-SIDDHA MODULE IN THE MANAGEMENT OF TYPE 2 DIABETES MELLITUS

Background: Diabetes causes serious global health burden, with cases projected to rise substantially in the coming decades, emphasizing the need for effective management strategies. The holistic traditional Indian systems, Siddha and Yoga approaches the individual rather than disease and can be integrated into diabetes care.

Aim: To evaluate the effect of integrated YoSi (Yoga and Siddha) Module in the management of Type 2 diabetes (T2DM)

Methods: 108 diabetic subjects attending Siddha OPD, Govt of Puducherry satisfying inclusion criteria were divided into two groups. YoSi (Experimental) group (n =54) received Yoga intervention alongside standard Siddha medication while the Siddha (Control) group (n=54) received only Siddha medication for four months. Both groups were advised diet and life style. Assessments included Body Mass Index (BMI), Waist circumference (WC), Heart rate, Fasting blood sugar (FBS), Postprandial blood sugar (PPBS), HbA1c, Fasting Insulin, HOMA-IR , Lipid profile, Urea, Creatinine, Perceived stress scale (PSS), Quality of life (QoL) and Siddha parameter Neikuri

Results: The mean age of participants in YoSi Module and Siddha group were 51.00±9.31 yrs and 52.75±9.5 yrs respectively. Both groups showed significant reduction in PPBS, HbA1c, fasting insulin, HOMA-IR and total cholesterol. The YoSi Module, in addition, exhibited significant reduction in FBS and BMI with delta significance indicating a higher improvement in fasting insulin, HOMA-IR, HDL and LDL. YoSi Module also demonstrated higher delta significance in Psychological parameters such as PSS and QoL. Neikuri analysis indicated a good prognosis in both groups. $P<0.05$ is considered significant

Conclusion: Integration of traditional therapeutic modalities such as Yoga and Siddha has shown beneficial impact on BMI, Glycemic indices, Lipid profile, Perceived stress and QoL which establish scientific evidence highlighting the potential of YoSi integration in T2DM. The YoSi module could be a valuable addition to diabetes care.

Keywords: YoSi, Diabetic complications, Glycemic indices, Insulin resistance, Neikuri

1. Introduction

1.1 Background

Diabetes is a chronic metabolic disorder that presents a serious public health concern worldwide marked by elevated blood glucose level due to defects in secretion of insulin or its action or both and if not treated causes serious damage, dysfunction and failure of different organs, especially the eyes, kidneys, nerves, heart and blood vessels.[1] The projection of 783 million adults living with diabetes by 2045 as indicated by the International Diabetes Federation (IDF), highlights a significant and concerning rise in the prevalence of this chronic condition which is closely linked to lifestyle factors like poor diet, physical inactivity, and obesity. [2] Since diabetes is increasingly prevalent in India, there is an immediate requirement for scientific studies and interventions to minimize the potentially disastrous rise in the illness that is expected in the years to come. [3] Diabetic patients are in need of holistic health care with equal weightage to mental health and quality of life as much as their physical health which must be emphasised. [4]

1.2 Pathophysiology of Type 2 Diabetes

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance, progressive beta-cell dysfunction and hyperglycemia**.** In the early stages, peripheral tissues such as skeletal muscle, liver and adipose tissue develop resistance to insulin reducing glucose uptake and increasing hepatic glucose production. To compensate, pancreatic beta-cells initially increase insulin secretion, but over time they undergo dysfunction and apoptosis leading to relative insulin deficiency. Additionally, impaired incretin function, increased lipolysis, chronic low-grade inflammation and renal glucose reabsorption further contribute to hyperglycemia. These metabolic abnormalities result in long-term complications, including microvascular and macrovascular complications. Understanding the intricate pathophysiology of T2DM is crucial for developing targeted therapeutic approaches to improve glycemic control and prevent complications.

1.3 Need for integration of Traditional systems of medicine

Traditional therapies expand beyond physical treatments to include psychological support to enhance overall heath, wellbeing and quality of life in individuals. By addressing the emotional and psychological challenges of diabetes, clinicians can reduce the disease burden and help the patients to better manage their condition and improve overall well-being.[5] To effectively combat the diabetes epidemic in India, it is crucial to implement a multifaceted approach, which includes enhancing preventive strategies and promoting medication adherence. Integrating traditional medical practices such as Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy (AYUSH) into both preventive and management protocols is becoming increasingly recognized as a valuable strategy to tackle this widespread health crisis.[6]

1.4 The potential of Yoga and Siddha medicine in T2DM

Yoga and Siddha are both traditional therapeutic modalities gifted to mankind by Seers and Siddhars who practiced yoga as a form of kayakarpam.[7] They are interrelated with each other treats individual as a whole and not the disease and share similarities of concepts such as tridoshas, trigunas, chakras and nadis and teaches various disciplines for healthy wellbeing and unique in its holistic approach. Studies shows that yoga has holistic effects that can improve metabolic and psychological health, enhance insulin sensitivity, and help manage T2DM and its associated comorbidities and also emphasizes the potential of yoga interventions to enhance cardiovascular health in individuals at high risk for diabetes. [8, 9]

Diabetes is comparable to the term Madhumegam in Siddha medicine. [10] elaborated by Saint Yugi as one of the 21 varieties of Mega noigal in the book Yugi vaidhiya chintamani. Studies proves that Siddha medicine minimize the occurrence and other future complications arising due to diabetes. [11, 12] Yoga has always been a way of life practised from ancient times for longevity along with Siddha for healthy wellbeing. This study aims to integrate both the systems in bringing together the traditional combined effect of Yoga and Siddha to show positive effects in diabetes.

1.5 Purpose of the study

As traditional systems treat the individual holistically there is a need to understand its effect in all dimensions of health. Reviews show that only one observational study has been done integrating yoga and Siddha [13] to explore its potential in the management

of T2DM. The ancient integrated practice which is lacking in modern world paved the way to do this research integrating Yoga and Siddha, further initiating scientific studies paving the way for realizing the full potential of AYUSH Systems in public health.

2. Aims & Objectives

2.1 Aim

To study the effect of integrated YoSi Module in the management of T2DM. (YoSi – the Acronym used to describe- Yo –Yoga and Si –Siddha for 'Integrated yoga siddha module')

2.2 Objectives

To evaluate the effect of integrated YoSi Module on

- Anthropometric parameters - Body Mass Index (BMI), Waist circumference (WC)
- Physiological parameters - Heart rate (HR), Systolic blood pressure (SBP) and Diastolic blood pressure (DBP)
- Biochemical parameters - Fasting blood sugar (FBS), Post prandial blood sugar (PPBS), HbA1c, Fasting Insulin, Homeostatic Model Assessment for Insulin Resistance (HOMA-IR), Lipid profile, Blood urea and Serum creatinine
- Psychological parameters - Perceived stress scale (PSS), Quality of life (WHOQOL-BREF)
- Traditional siddha parameter - Neikuri

3. Research Question

Will an integrated YoSi Module be effective in management of T2DM?

4. Brief Review of Literature

A number of studies have highlighted the beneficial effects of yoga in improving various metabolic parameters such as blood glucose levels, insulin resistance, and lipid profiles. This review aims to synthesize the findings regarding the impact of yoga on key physiological and psychological aspects of T2DM management.

Dewangani et al review suggest yoga as one of the lifestyle intervention practice proved to show beneficial effects in the prevention and management of T2DM through the

improvement of weight, BP, glycemic parameters, lipid profile, and oxidative stress.[14] Gowri et al concluded that integrated yoga therapy showed significant results in glycemic control, insulin resistance, and key biochemical parameter and recommended yoga to be practiced as an adjuvant and non-invasive therapy to manage diabetes.[15] Dhali et al meta-analysis states that yoga group showed significant reduction in FBS by 33.02 mg/dl, PPBS by 62.54 mg/dl fasting insulin by 4.95 µIU/mL and insulin resistance (HOMA-IR) 2.81 when compared with control group.[16]

A meta-analytic study highlights that yoga has more significant effects on glycemic control and insulin resistance in comparison to walking in the T2DM. [17] Kaur et al suggests that yoga intervention enhances the metabolic health of individuals at high risk for diabetes, emphasizing its potential in improving the cardiovascular health. [18] Raveendran et al demonstrates the scientific evidence of holistic effects by highlighting the potential benefits of yoga-based lifestyle changes in controlling T2DM and its related risk factors. Further the study emphasis that yoga works through psychoneuro-endocrine and immune mechanisms, parasympathetic activation and stress management strategies, enhance overall metabolic and psychological health improving insulin sensitivity, glucose tolerance, and lipid metabolism. Practices like asanas, pranayama, and meditation reduce blood glucose and help manage diabetes-related conditions, leading to positive clinical outcomes. [19]

Another study states that yoga provides a comprehensive approach to manage T2DM and its complications by providing a combination of asanas, pranayama, meditation, kriyas, sattvic diet, mental discipline and promote lifestyle changes to combat diabetes. [20] Keerthi et al study shows that Yoga intervention along with standard medical management improved QoL and decreased the diabetes complications. [21]

Vijayakumar et al shows that Siddha medicine proves significant effects in reducing blood sugar level and diabetic complications as it treats the individual holistically.[22] An observational study demonstrated that combined Siddha medicine and yoga along with allopathic medications showed positive effects on T2DM suggesting the need for clinical trials and long-term research studies.[13]

Javed et al recommends the implementation of Ayush therapies with evidence-based research thereby integrative medicine into the mainstream will revolutionize the healthcare system. [23]

In summary, Yoga has been shown to have significant benefits in managing T2DM by improving key metabolic parameters such as blood glucose levels, insulin resistance (IR), and lipid profiles. Additionally, yoga contributes to weight management, lowers blood pressure, and improves overall cardiovascular health. Yoga also plays a vital role in stress management and psychological well-being, which are crucial factors in managing diabetes. Practices like asanas, pranayama, and meditation are particularly effective in enhancing insulin sensitivity, glucose tolerance, and metabolic health. Yoga has been found to improve the QoL of individuals with diabetes by reducing complications and promoting a balanced, healthy lifestyle.

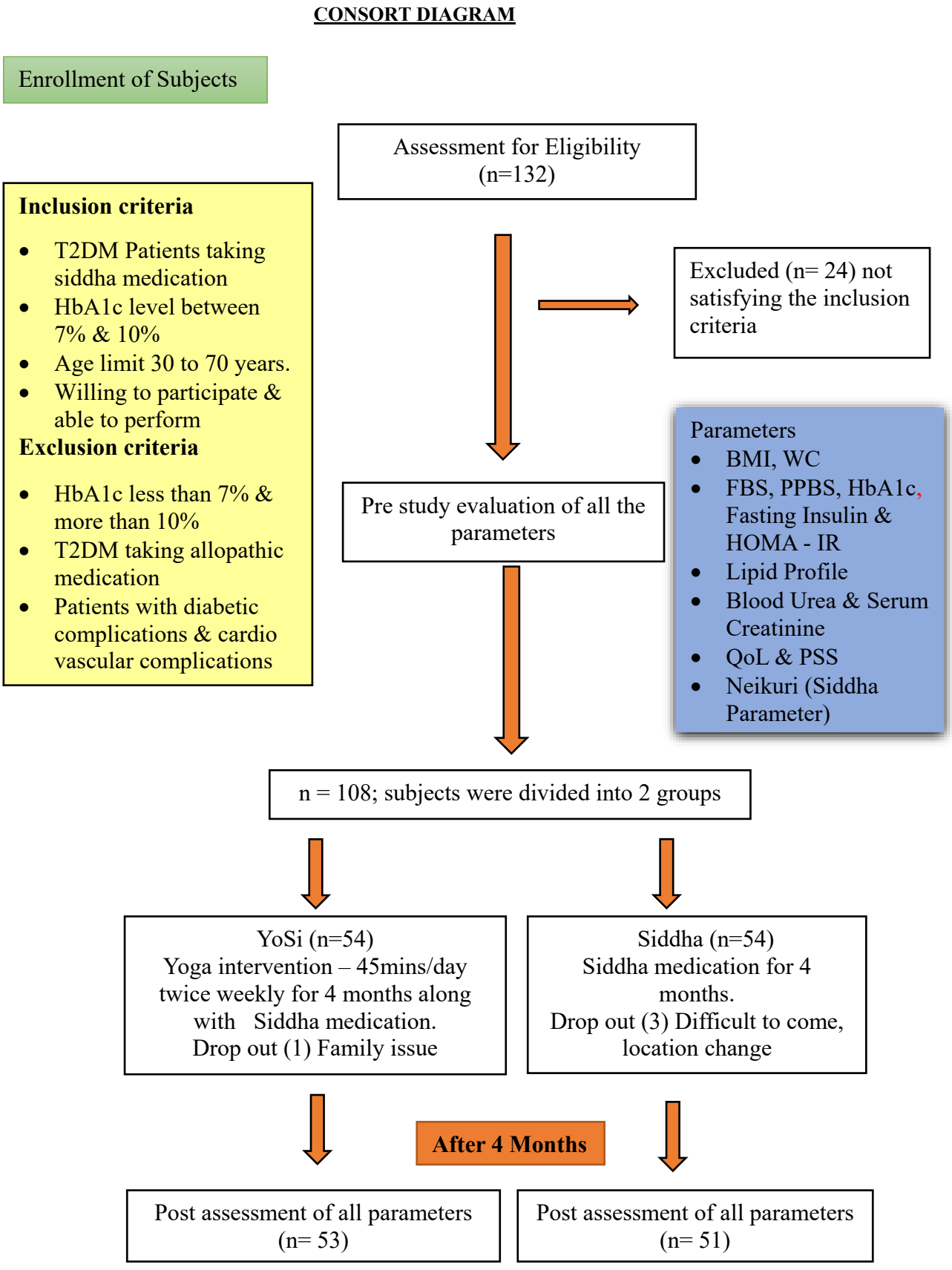
Moreover, studies on integrated approaches combining yoga with other traditional Ayush therapies, such as Siddha medicine, have also shown positive results in managing diabetes-related complications further revolutionize diabetic care by promoting integrative medicine.

5. Methodology

5.1 Consort chart

The methodology of the study has been shown in the CONSORT diagram (Figure 1). It illustrates the flow of the participants through the study, including the number of participants screened, excluded, randomized, and analysed. This figure provides a clear and concise overview of the study design and participant flow and serves as a useful reference for interpreting the main findings of the trial.

Figure 1: CONSORT flow diagram of study recruitment of subjects with T2DM


CONSORT DIAGRAM
Enrollment of Subjects
Assessment for Eligibility (n=132)
Inclusion criteria
T2DM Patients taking siddha medication
HbA1c level between 7% & 10%
Age limit 30 to 70 years.
Willing to participate & able to perform
Exclusion criteria
HbA1c less than 7% & more than 10%
T2DM taking allopathic medication
Patients with diabetic complications & cardio vascular complications
Excluded (n= 24) not satisfying the inclusion criteria
Parameters
BMI, WC
FBS, PPBS, HbA1c, Fasting Insulin & HOMA - IR
Lipid Profile
Blood Urea & Serum Creatinine
QoL & PSS
Neikuri (Siddha Parameter)
Pre study evaluation of all the parameters
n = 108; subjects were divided into 2 groups
YoSi (n=54)
Yoga intervention – 45mins/day twice weekly for 4 months along with Siddha medication.
Drop out (1) Family issue
Siddha (n=54)
Siddha medication for 4 months.
Drop out (3) Difficult to come, location change
After 4 Months
Post assessment of all parameters (n= 53)
Post assessment of all parameters (n= 51)

5.2 Study Design

This study was a True experimental design (Two groups pre-post test design) which assigns participants into an experimental group (YoSi) or a control group (Siddha). The study was approved by the Institutional Human Ethical Committee (IHEC) (PhD PROJECT /08/2019/008 dated 23/08/2019) and registered with the Clinical Trials Registry of India (CTRI/2020/03/024086).

5.3 Place of Study

The study was done at Siddha Unit, Primary Health Centre, Reddiarpalayam, Government of Puducherry.

5.4 Patient selection

5.4.1 Study Population

The Study involves diabetic subjects attending Siddha OPD satisfying inclusion criteria in PHC Reddiarpalayam, Govt of Puducherry.

5.4.2 Inclusion criteria

- Patients with T2DM taking siddha medication
- HbA1c level between 7% and 10%
- Age limit 30 years to 70 years.
- Able to perform the technique in the protocol.
- Willing to participate in yoga therapy.

5.4.3 Exclusion criteria

- HbA1c less than 7% and more than 10%
- Patients with T2DM taking allopathic medication
- Patients with clinical manifested evidence of diabetic complications, cardiovascular complications such as uncontrolled hypertension, myocardial infarction, mitral prolapse

5.4.4 Study Subjects

The Study involves newly diagnosed diabetic subjects attending Siddha OPD satisfying inclusion criteria in PHC Reddiarpalayam, Govt of Puducherry.

5.4.5 Sample Size

The mean FBS level after a routine treatment for T2DM patients in yoga intervention group was taken as pre 168.30 ±14.86 and that for post 158.50 ± 11.70 from review of literature (Mondal et al).[24] By assuming a α = 0.05 and β = 0.05 and by using the formula

$$n = \frac{\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 * ({\sigma_1}^2 + {\sigma_2}^2)}{(\mu_1 - \mu_2)^2}$$

Where,

$Z_{1-\alpha/2} = 1.96\ at\ 95\%\ of\ confidence\ with\ \alpha = 0.05$

$Z_{1-\beta} = 1.64\ at\ 95\%\ of\ power\ with\ \beta = 0.05$

$\mu_1 = 168.3; \sigma_1 = 14.86\ and\ \mu_2 = 158.5;\ \sigma_2 = 11.70\ from\ previous\ study$

$$n = \frac{(1.96 + 1.64)^2 * (14.86^2 + 11.70^2)}{(168.3 - 158.5)^2}$$

$$n = 49$$

The sample size comes to 49 per group. With an expected attrition rate of 10% the sample size comes to 54 per group. This study has two groups, the total sample size becomes 108 T2DM patients

5.4.6 Sampling procedure

Purposive sampling procedure was followed

5.5 Patient Allocation/Randomisation

The diabetic subjects (n=108) were divided into two groups namely YoSi group (Integrated Yoga - Siddha module) (n=54) & Siddha group (Siddha Medical Management) (n=54) through voluntary based selection. Siddha group received the

Siddha medication for a period of 4 months while YoSi group received Yoga therapy intervention along with Siddha medication for a period of four months.

5.6 Outcome Measures/ Tools Used

S.No	Parameters	Variables
1	Anthropometry	BMI and waist circumference
2	Physiological	Heart rate, systolic and diastolic blood pressure
3	Bio- chemical	FBS, PPBS, HbA1c, Fasting Insulin, HOMA-IR, Lipid profile, Blood urea & serum creatinine
4	Psychological (Questionnaires)	PSS & WHOQOL-BREF
5	Traditional parameter	Neikuri (Siddha diagnostic and prognostic tool)

5.6.1Anthropometric Parameters

Height:

Height was measured using a Stadiometer [Easy care TM (NO: 26 SM)] mounted on the wall. The precise height in centimeters was recorded.

Weight:

Weight was calculated using an automated weighing instrument (Charder Electronics, Taichung, Taiwan 2013), which has a maximum weight restriction of 300 kg and a minimum weight limit of 2 kg.

BMI

BMI was calculated using the formula

$$BMI = \frac{\text{Weight in Kilograms}}{\text{Height in Metres}^2}$$

Waist Circumference

Using a flexible narrow non- stretch tape in adults wearing minimal clothing

Waist circumference (WC) was measured by placing around the waist in line with the navel. It was recorded in centimetres.

5.6.2 Physiological parameters

Heart rate (HR) and blood pressure (BP) were recorded utilising non-invasive automatic blood pressure (BP) monitor (Omron HEM 7203, Kyoto, Japan) using oscillometric method with accuracy of ± 5% for HR and ± 3 mm Hg

5.6.3 Biochemical Parameters

All biochemical tests were done at Indira Gandhi Government General Hospital laboratory, Puducherry by qualified technicians and analysed for the results.

Homeostatic Model Assessment for Insulin Resistance (HOMA-IR)

Insulin Resistance was assessed using the formula

$$Fasting\ Insulin \times Fasting\ glucose/22.5$$

5.6.4 Psychological assessment

Perceived Stress Scale (PSS)

To assess the stress level of the individual PSS was used. This is a 10-item questionnaire with score ranging from 0 to 40. Greater scores correspond to higher levels of perceived stress. [25]

Quality of Life (WHOQOL - BREF)

To assess the quality of life, WHOQOL - BREF scale was used which was a 26-item tool that addresses Physical, psychological, social and Environmental dimensions of health measured by a five point ordinal scale, ranging from 1 to 5 and scores are linearly transformed to generate a 0–100 scale and higher scores indicate better QoL. [26]

5.6.5 Traditional Siddha Parameter

Neikuri

Neikuri is one of the eight siddha diagnostic tools (Envagai thervu) stated by Saint Theraiyar. Urine examination in Siddha System is a unique technique to evaluate the condition of individual from normal to pathological state. It plays a significant role in diagnosis and prognosis of a disease. [27]

Neikuri procedure

About 100ml of urine sample which was collected in a sterile, clean, dry container was placed in a circular glass petri dish undisturbed by wind, and a drop of black sesame seed oil was gently dropped on the sample. The pattern of oil spreading on urine was watched carefully, and results were analyzed according to the nature of spread. [28] The entire procedure was recorded in the form of video clips and photos were taken for proper evaluation.

5.7 Yoga Therapy Protocol

Based on yoga practises at School of Yoga Therapy, Institute of Salutogenesis and Complementary Medicine [erstwhile CYTER] the following practices were selected after expert validation (Table 1).

Table 1: Yoga therapy protocol

S.No	Yogic Techniques	Repetition(Rounds)	Duration (min)
1.	Prayer		
2.	Jathis / Warming up	3 times each	5
3.	Talasana	3 times	2
4.	Trikonasana	3 times	3
5.	Arthakatichakrasana	3 times	3
6.	Vakrasana	3 times	3
7.	Jataraparivrittanasana	3 times	3
8.	Pavanamukthanasana	3 times	3
9.	Viparitakarani	3 times	3
10.	Nadishuddhi	9 rounds	5
11.	Brahmari	9 rounds	5
12.	Marmanasthanam kriya (Relaxation of each body part focusing from toes to head)	1 round	10
Total duration			45 mins

5.8 Procedure/Conduct of the Study

- The newly diagnosed diabetic subjects who attended Siddha OPD were detailed about the study & its significance and after getting consent they were screened for eligibility based on Inclusion & Exclusion criteria.
- The eligible subjects were grouped into integrated YoSi group and Siddha group of 54 subjects in each group through voluntary based selection. Orientation program was conducted.
- YoSi group was given yoga intervention (Supervised yoga sessions) twice weekly for 4 months and subjects were motivated to practice yoga techniques every week when they come for follow up
- Siddha group was given Siddha medicine alone for 4 months.
- Both YoSi group and Siddha group were followed up regularly once a week for their compliance with medicines and yoga intervention.
- Pre and post data were collected before and after intervention.
- Siddha parameter Neikuri was analysed before and after intervention.
- No complications were found throughout the study
- Diet and lifestyle were advised for both the groups.

5.9 Statistical Analysis

The data was collected and recorded through MS Excel 2021 & Statistical analysis was carried out using SPSS 16.0 version. Frequency and percentage was used to represent Categorical data. Mean and Standard deviation was used to represent quantitative data. Independent t-test was used to find the significance between groups. Paired t-test was used to find the significance within groups. Chi-square test was used to check the association between two factors. For demographic variables - Correlation test, Independent t test, ANOVA test was used to find the association between clinical variables and demographic variables. For Neikuri - Wilcoxon test was used to find the significance between pre and post test, Mann-witney test was used to find the significance between the groups, Kruskal wallis test was used to find the significance between the Neikuri groups. p value <0.05 was considered as significant

6. Results

Baseline comparison of demographic variables

Table 2: Gender distribution of the subjects in YoSi and Siddha group

Gender	Group		Total	Chi-Square test	p-value
	YoSi	Siddha			
Female	28 (26.9%)	20 (19.2%)	48(46.2%)	1.938	0.164
Male	25(24%)	31(29.8%)	56(53.8%)		
Total	53(51%)	51(49%)	104(100%)		

Table 3: Age distribution of the subjects in YoSi and Siddha group

	Group	Mean	SD	SE	Independent Samples t-test	p-value
Age	YoSi	51.00	9.31	1.28	-0.942	0.349
	Siddha	52.75	9.59	1.34		

Table 4: Demographic variables (Education, Marital status, Religion, Economic status, Family type, Employment, Family history) between YoSi and Siddha groups

Variables		YoSi (n = 53)		Siddha (n = 51)		Chi-square	p value
		Count	Percentage	Count	Percentage		
Education	Illiterate	5	9.4%	10	19.6%	5.792	0.215
	Primary	12	22.6%	18	35.3%		
	Hr. Secondary	19	35.8%	13	25.5%		
	UG	14	26.4%	8	15.7%		
	PG	3	5.7%	2	3.9%		
Marital status	Married	47	88.7%	44	86.3%	1.505	0.681
	Unmarried	1	1.9%	0	0.0%		
	Widow	4	7.5%	5	9.8%		
	Widower	1	1.9%	2	3.9%		
Religion	Christian	3	5.7%	10	19.6%	4.664	0.097
	Hindu	48	90.6%	39	76.5%		
	Muslim	2	3.8%	2	3.9%		
Economic status	Lower Cl	29	54.7%	31	60.8%	0.392	0.531
	Middle Cl.	24	45.3%	20	39.2%		
Family type	Extended	14	26.4%	12	23.5%	0.115	0.734
	Nuclear	39	73.6%	39	76.5%		
Employment	Employed	24	45.3%	24	47.1%	0.282	0.963
	Housewife	20	37.7%	17	33.3%		
	Retired	3	5.7%	3	5.9%		
	Unemployed	6	11.3%	7	13.7%		
Family history	No	13	24.5%	11	21.6%	0.128	0.72
	Yes	40	75.5%	40	78.4%		

$P<0.05$ is considered significant

Table 5: Baseline Comparison of Anthropometric, Glycemic, Lipid, Renal, PSS & QoL parameters between YoSi & Siddha groups

Parameters	YoSi (n = 53)		Siddha (n = 51)		Independent t-test	p value
	Mean	SD	Mean	SD		
Weight(kg)	65.71	10.51	66.52	10.73	-0.390	0.697
BMI	25.51	4.02	26.76	5.31	-1.355	0.178
WC (cm)	94.28	8.31	95.90	8.90	-0.959	0.340
HR (bpm)	86.09	9.00	83.06	8.09	1.807	0.074
SBP (mmHg)	133.15	17.26	136.57	21.04	-0.907	0.366
DBP (mmHg)	84.43	9.09	84.61	9.89	-0.093	0.926
FBS (mg/dl)	178	50.01	171.43	50.31	0.668	0.506
PPBS (mg/dl)	270.59	70.18	274.29	72.37	-0.265	0.791
HbA1C (%)	8.29	1.04	8.18	0.96	0.541	0.589
Fasting Insulin(μIU/ml)	9.08	3.44	9.03	3.84	0.070	0.944
HOMA – IR	4.02	2.02	3.69	1.57	0.930	0.354
Cholesterol (mg/dl)	207.26	42.27	215.26	48.18	-0.900	0.370
HDL (mg/dl)	40.34	6.50	41.06	5.82	-0.594	0.554
LDL (mg/dl)	142.34	28.40	142.31	39.63	0.004	0.997
TG (mg/dl)	152.51	90.02	150.65	80.62	0.111	0.912
Urea(mg/dl)	22.89	4.02	23.41	3.7	-0.692	0.491
Creatinine (mg/dl)	0.99	0.2	1.04	0.13	-1.681	0.096
PSS	20.11	4.85	19.84	4.27	0.301	0.764
BREF 1 Physical domain	45.25	15.41	48.78	14.64	-1.200	0.233
BREF 2 Psychological domain	63.98	13.98	60.57	9.96	0.758	0.257
BREF 3 Social domain	45.91	18.73	48.63	16.40	-1.704	0.197
BREF 4 Environmental domain	50.81	12.88	51.71	11.50	-0.373	0.710

BMI- Body Mass Index; WC- waist Circumference; HR- Heart rate; SBP- Systolic blood pressure ; DBP- Diastolic blood pressure FBS- Fasting Blood Sugar; PPBS- Post Prandial Blood Sugar; HbA_1c- Glycosylated Hemoglobin; HOMA IR- Homeostatic Model Assessment for Insulin Resistance; HDL- High Density Lipid; LDL- Low Density Lipid ; TG- Triglycerides; PSS- Perceived Stress Scale $p<0.05$ is considered significant

Table 6: Comparison of Anthropometric parameters between YoSi & Siddha groups before & after 4 months of study period

Parameters	Period	YoSi (n = 53)		Siddha (n = 51)		Independent t-test	p-value
		Mean	SD	Mean	SD		
Weight (kg)	Pre test	65.71	10.51	66.52	10.73	-0.390	0.697
	Post test	63.43	9.49	66.03	10.48	-1.325	0.188
	Paired t-test	7.935		1.513			
	p value	**< .001**		0.137			
BMI	pre test	25.51	4.02	26.76	5.31	-1.355	0.178
	post test	24.63	3.60	26.56	5.18	-2.210	**0.029**
	Paired t-test	7.862		1.630			
	p value	**< .001**		0.109			
WC (cm)	pre test	93.68	8.03	95.90	8.90	-0.959	0.340
	post test	91.02	7.17	94.39	7.75	-3.030	**0.003**
	Paired t-test	4.645		2.801			
	p value	**< .001**		**0.007**			
HR (bpm)	pre test	86.09	9.00	83.06	8.09	1.807	0.074
	post test	81.23	5.84	80.47	6.13	0.644	0.521
	Paired t-test	6.158		5.273			
	p value	**< .001**		**< .001**			
SBP (mmHg)	pre test	133.15	17.26	136.57	21.04	-0.907	0.366
	post test	126.76	11.82	129.63	12.91	-1.184	0.239
	Paired t-test	4.433		4.248			
	p value	**< .001**		**< .001**			
DBP (mmHg)	pre test	84.43	9.09	84.61	9.89	-0.093	0.926
	post test	79.72	5.79	79.67	6.09	0.043	0.966
	Paired t-test	4.988		5.741			
	p value	**< .001**		**< .001**			

P<0.05 is considered significant

Table 7: Comparison of Glycemic parameters between YoSi & Siddha groups before & after 4 months of study period

Parameters	Period	YoSi (n = 53)		Siddha (n = 51)		Independent t-test	p-value
		Mean	SD	Mean	SD		
FBS (mg/dl)	pre test	178	50.01	171.43	50.31	0.668	0.506
	post test	159.34	43.68	156.94	43.88	0.279	0.781
	Paired t-test	3.250		1.829			
	p value	**0.002**		0.073			
PPBS (mg/dl)	pre test	270.59	70.18	274.29	72.37	-0.265	0.791
	post test	233.53	65.28	237.59	66.30	-0.315	0.754
	Paired t-test	4.033		3.437			
	p value	**< .001**		**0.001**			
HbA1c (%)	pre test	8.29	1.04	8.18	0.96	0.541	0.589
	post test	7.30	1.00	7.4	0.83	-0.542	0.589
	Paired t-test	8.112		6.096			
	p value	**< .001**		**< .001**			
Fasting Insulin (µIU/ml)	pre test	9.08	3.44	9.03	3.84	0.070	0.944
	post test	5.75	2.27	7.02	3.45	-2.219	**0.029**
	Paired t-test	7.744		4.561			
	p value	**< .001**		**< .001**			
HOMA - IR	pre test	4.02	2.02	3.69	1.57	0.930	0.354
	post test	2.30	1.20	2.71	1.61	-1.480	0.142
	Paired t-test	8.340		3.816			
	p value	**< .001**		**< .001**			

P<0.05 is considered significant

Table 8: Comparison of Lipid and Renal parameters between YoSi & Siddha groups before & after 4 months of study period

Parameters	Period	YoSi (n = 53)		Siddha (n = 51)		Independent t-test	p-value
		Mean	SD	Mean	SD		
Cholesterol (mg/dl)	pre test	207.26	42.27	215.26	48.18	-0.900	0.370
	post test	183.15	32.38	197.78	34.01	-2.248	**0.027**
	Paired t-test	5.648		4.251			
	p value	**< .001**		**< .001**			
HDL (mg/dl)	pre test	40.34	6.50	41.06	5.82	-0.594	0.554
	post test	43.19	4.84	41.31	5.21	1.903	0.060
	Paired t-test	-3.110		-0.394			
	p value	**0.003**		0.695			
LDL (mg/dl)	pre test	142.34	28.40	142.31	39.63	0.004	0.997
	post test	126.66	22.37	135.80	22.75	-2.067	**0.041**
	Paired t-test	5.730		1.945			
	p value	**< .001**		0.057			
TG (mg/dl)	pre test	152.51	90.02	150.65	80.62	0.111	0.912
	post test	143.17	69.15	145.90	61.88	-0.212	0.832
	Paired t-test	0.968		0.692			
	p value	0.337		0.492			
Urea(mg/dl)	pre test	22.89	4.02	23.41	3.7	-0.692	0.491
	post test	22.30	4.34	22.77	3.45	-0.600	0.550
	Paired t-test	0.873		0.924			
	p value	0.387		0.360			
Creatinine (mg/dl)	pre test	0.99	0.2	1.04	0.13	-1.681	0.096
	post test	1.04	0.16	1.04	0.14	-0.177	0.860
	Paired t-test	-2.264		-0.101			
	p value	**0.028**		0.920			

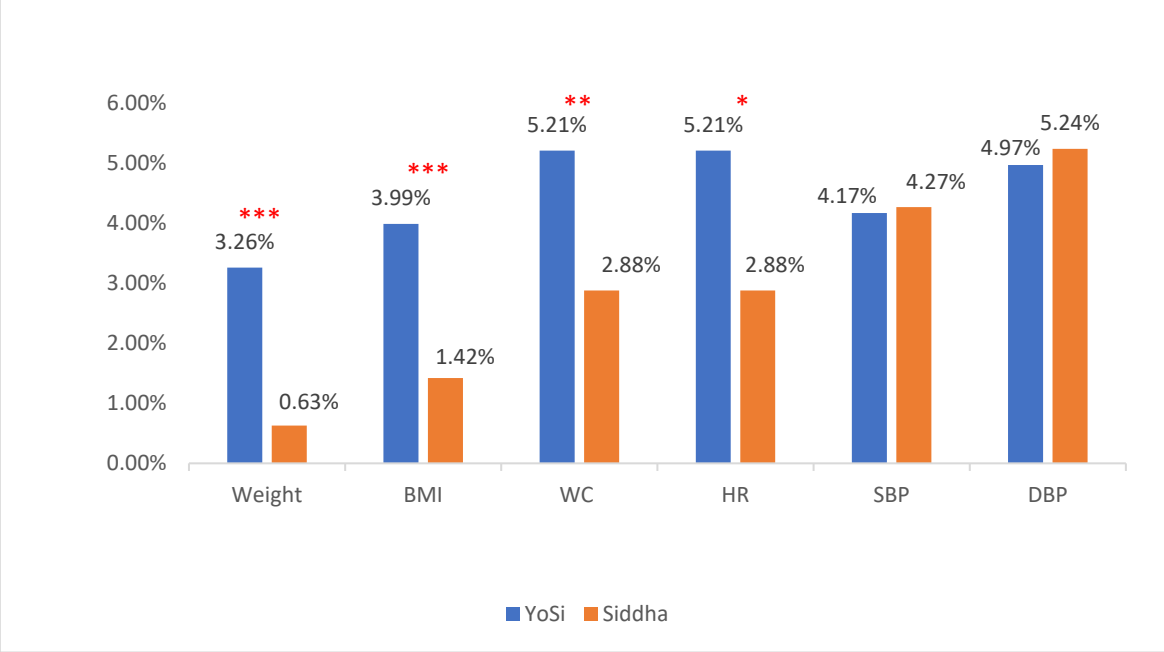
P<0.05 is considered significant

Table 9: Comparison of PSS & QoL parameters between YoSi & Siddha groups before & after 4 months of study period

Parameters	Period	YoSi (n = 53)		Siddha (n = 51)		Independent t-test	p-value
		Mean	SD	Mean	SD		
PSS	pre test	20.11	4.85	19.84	4.27	0.301	0.764
	post test	10.40	3.33	13.26	3.85	-4.206	**< .001**
	Paired t-test	17.428		9.357			
	p value	**< .001**		**< .001**			
BREF 1 Physical domain	pre test	45.25	15.41	48.78	14.64	-1.200	0.233
	post test	74.59	14.54	68.61	12.51	2.243	**0.027**
	Paired t-test	-11.009		-7.718			
	p value	**< .001**		**< .001**			
BREF 2 Psychological domain	pre test	63.98	13.98	60.57	9.96	0.758	0.257
	post test	78.49	11.76	69.31	11.91	3.955	**< .001**
	Paired t-test	-10.492		-4.410			
	p value	**< .001**		**< .001**			
BREF 3 Social domain	pre test	45.91	18.73	48.63	16.40	-1.704	0.197
	post test	73.06	11.8	63.39	12.40	4.073	**< .001**
	Paired t-test	-15.461		-5.864			
	p value	**< .001**		**< .001**			
BREF 4 Environmental domain	pre test	50.81	12.88	51.71	11.50	-0.373	0.710
	post test	72	12.46	63.78	11.37	3.508	**< .001**
	Paired t-test	-11.850		-6.981			
	p value	**< .001**		**< .001**			

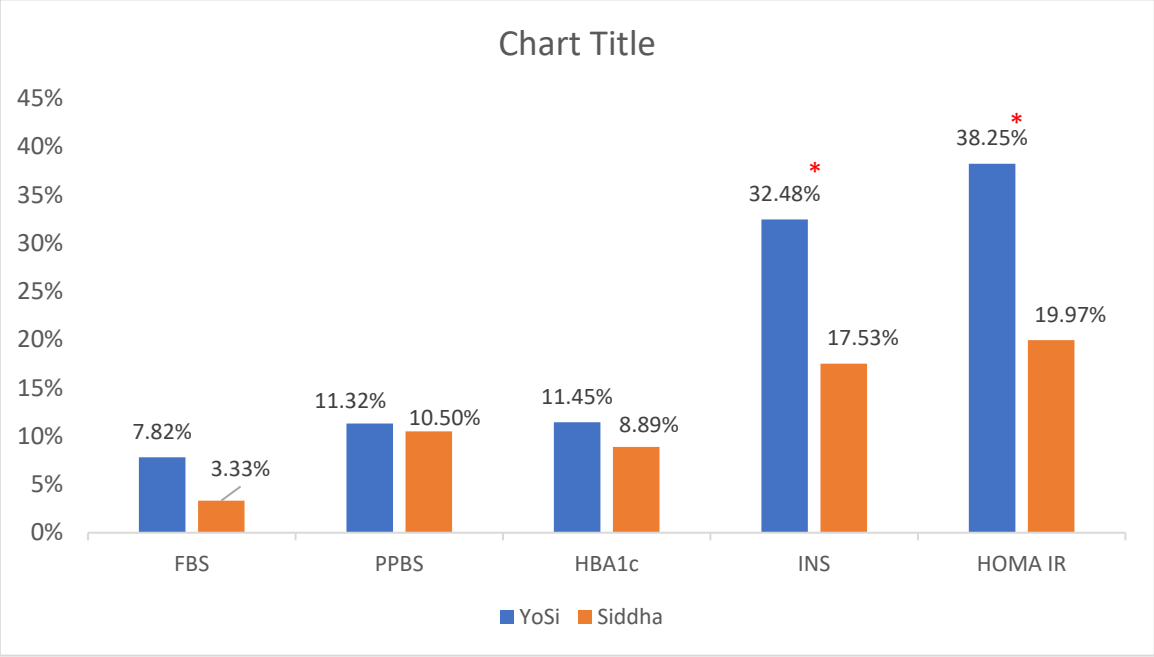
P<0.05 is considered significant

Figure 2: Delta percentage of improvement in Anthropometric variables between YoSi and Siddha group



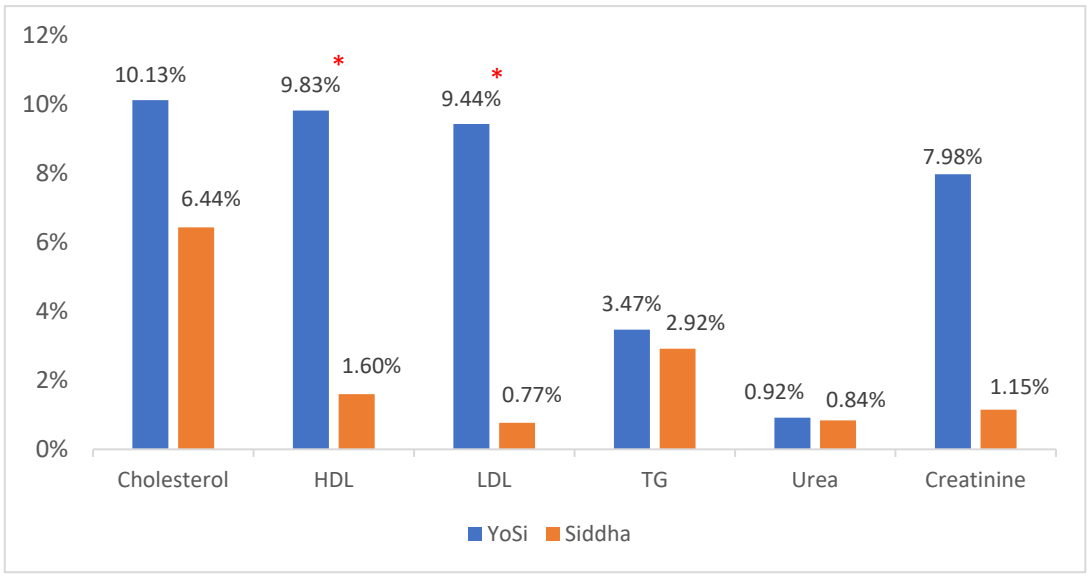
*P<0.05, **P<0.01 and ***P<0.001 is significant by Independent t-test for intergroup comparisons.

Figure 3: Delta percentage of improvement in Glycemic variables between YoSi and Siddha group



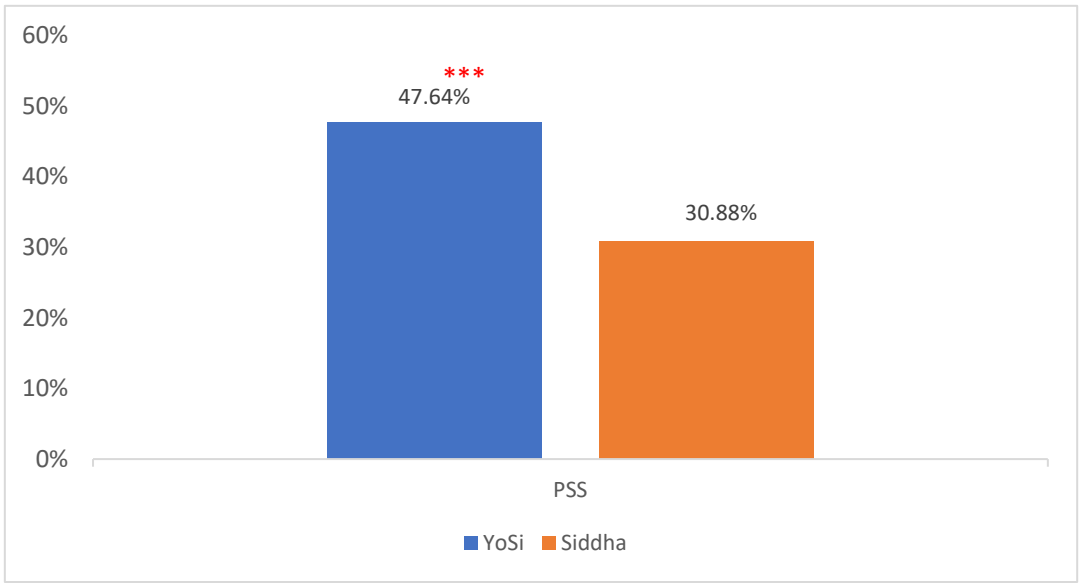
*P<0.05, **P<0.01 and ***P<0.001 is significant by Independent t-test for intergroup comparisons.

Figure 4: Delta percentage of improvement in Lipid and Renal variables between YoSi and Siddha group



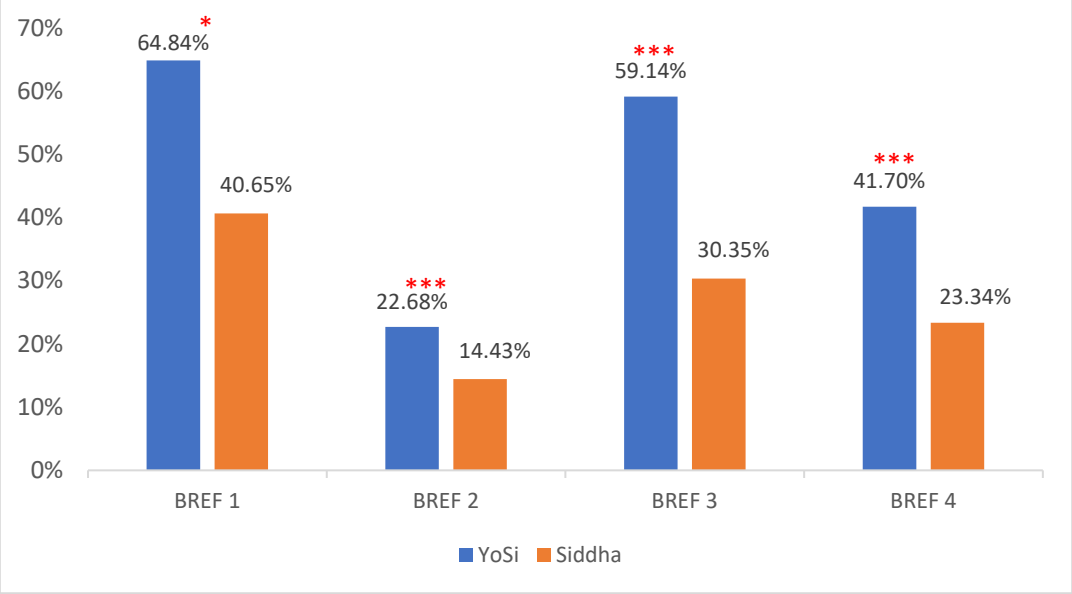
*P<0.05, **P<0.01 and ***P<0.001 is significant by Independent t-test for intergroup comparisons.

Figure 5: Delta percentage of improvement in PSS between YoSi and Siddha group



*P<0.05, **P<0.01 and ***P<0.001 is significant by Independent t-test for intergroup comparisons.

Figure 6: Delta percentage of improvement in QOL Scale between YoSi group and Siddha group



*P<0.05, **P<0.01 and ***P<0.001 is significant by Independent t-test for intergroup comparisons.

Figure 7: Forest plot of BMI from other studies

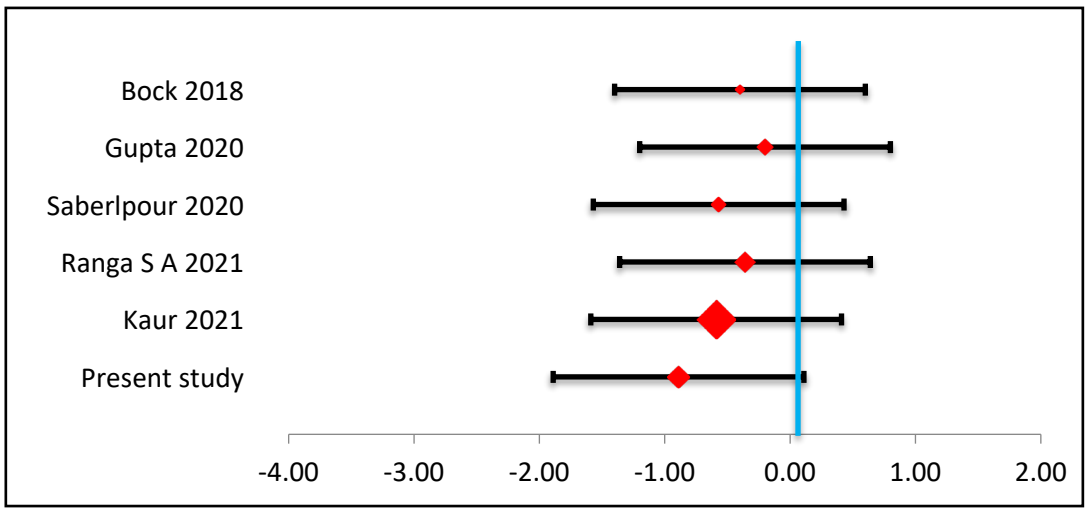


Figure 8: Forest plot of FBS from other studies

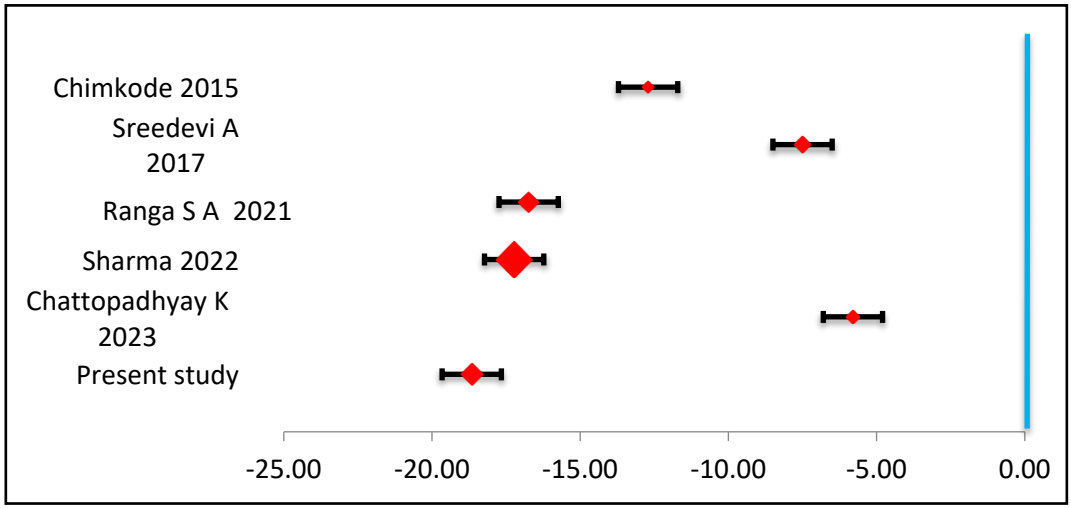


Figure 9: Forest plot of PPBS from other studies

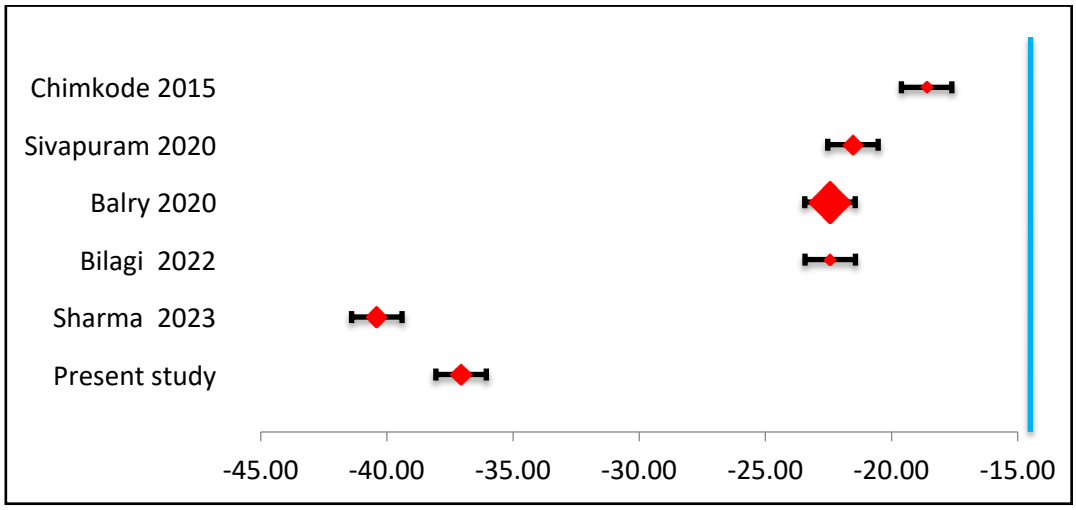


Figure 10: Forest plot of HbA1c from other studies

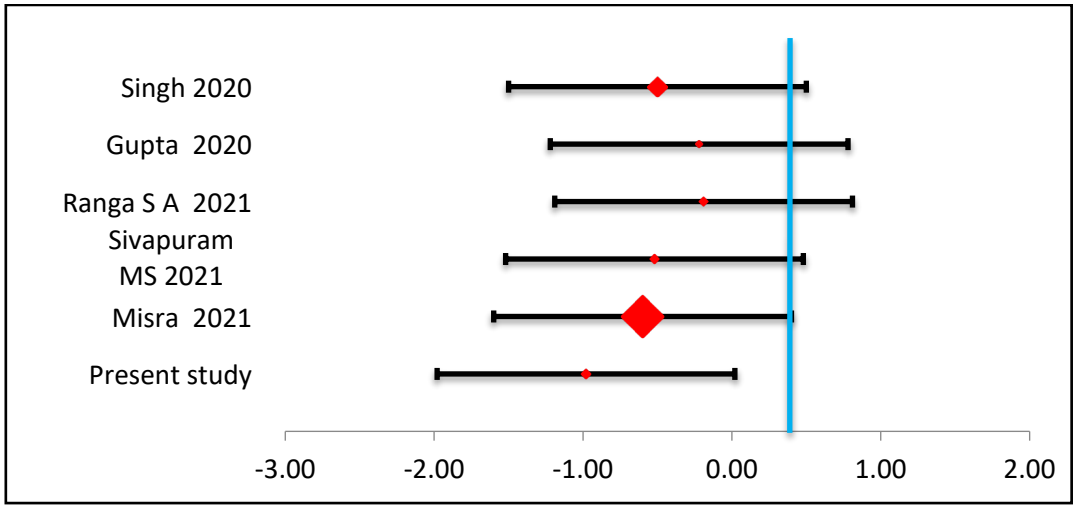


Figure 11: Forest plot of Fasting insulin from other studies

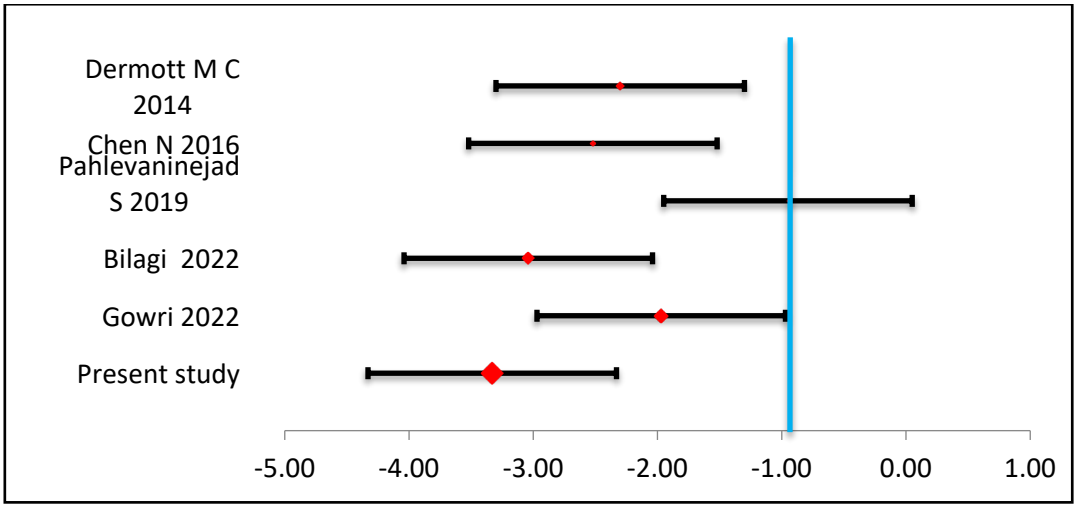
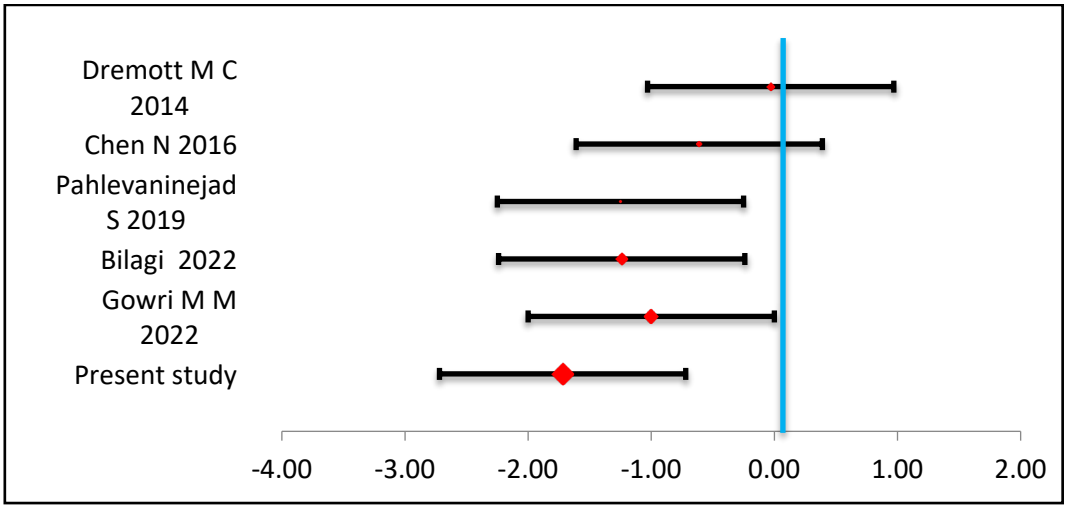


Figure 12: Forest plot of HOMA IR from other studies



Neikuri Analysis

Table 10: Analysis of the Mukkutram (Tridoshas) in Neikuri of YoSi and Siddha group before and after 4 months of study period

	YoSi (n=53)				Siddha (n=51)			
Kutram	Pre test		Post test		Pre test		Post test	
Analysis of Kutram	No of Subjects	N %	No of Subjects	N %	No of Subjects	N %	No of Subjects	N %
Kapham	5	9.3%	0	0%	3	5.9%	1	2.0%
Kaphapitham	7	13.2%	0	0%	3	5.9%	2	3.9%
Kaphavatham	2	3.8%	0	0%	7	13.7%	2	3.9%
Pitham	0	0%	46	86.8%	0	0%	33	64.7%
Pithakapham	9	17.0%	0	0%	11	21.6%	2	3.9%
Pithathilpitham	1	1.9%	3	5.7%	1	2.0%	7	13.7%
Pithavatham	3	5.7%	4	7.5%	4	7.8%	4	7.8%
Vathakapham	24	45.3%	0	0%	22	43.1%	0	0%
Vathapitham	2	3.8%	0	0%	0	0%	0	0%

Table 11: Analysis of the nature of spread, nature of shape and nature of direction in Neikuri of YoSi and Siddha group before and after 4 months of study period

Nature of spread		YoSi (n=53)				Siddha (n=51)			
		Pre test		Post test		Pre test		Post test	
		No of Subjects	N %	No of Subjects	N %	No of Subjects	N %	No of Subjects	N %
Analysis of Spread	Fast	43	81.2%	0	0%	38	74.5%	1	2.%
	Slow	5	9.4%	53	100%	6	11.8%	50	98%
	No spread	5	9.4%	0	0%	3	5.9%	0	0%
	Very Fast Half sink	0	0%	0	0%	4	7.8%	0	0%
Analysis of Shape	Circular	6	11.3%	53	100%	5	9.7%	49	96.1%
	Non-Circular	40	75.5%	0	0%	42	82.4%	2	3.9%
	Salladaikan	4	7.5%	0	0%	1	2%	0	0%
	No spread	3	5.7%	0	0%	3	5.9%	0	0%
Analysis of Uniformity	Uniform	7	13.2%	53	100%	4	7.8%	49	96.1%
	Non-Uniform	43	81.1%	0	0%	44	86.3%	2	3.90%
	No spread	3	5.7%	0	0%	3	5.9%	0	0%

7. Discussion

The results of this study underscore that YoSi Module plays a significant role in improving physiological and psychological parameters, enhancing metabolism, reducing stress, and improving overall quality of life of T2DM. In our study YoSi Module has demonstrated significant reduction in weight and BMI which play a crucial role in the management of T2DM. This was also stated by Nongkhai et al that continuous yoga practice was effective to prevent obesity [29] and Dewangani et al demonstrated that yoga plays a significant role in T2DM through the improvement of weight, BP, glycemic parameters, lipid profile, and oxidative stress. [14] YoSi Module showed significant results in reducing Waist circumference, Heart rate, Systolic blood pressure & diastolic blood pressure proving the effectiveness of Integration which was also stated by Bhupender et al study showing significant parasympathetic dominance. [30]

Siddha group showed comprehensive results reducing key biomarkers in diabetes management, such as PPBS, HbA1c, fasting insulin and HOMA IR. YoSi Module along with these showed significant results also in FBS and higher significance in Fasting Insulin and HOMA IR proving the combined effect of traditional systems shows significant improvement in glycemic control, IR, and biochemical parameters in DM. Gowri et al study demonstrated that integrated yoga therapy leads to significant improvement in glycemic control, insulin resistance, and biochemical parameters in DM.[15] Dhali et al meta-analysis delivers a strong indication that adjuvant yoga therapy has positive effects on IR and glycemic control in patients with T2DM. [16] This shows that the combination of the two appears to provide more comprehensive and statistically significant improvements particularly in fasting blood sugar, which is a critical parameter in diabetic care.

YoSi Module play a key role in boosting the beneficial effects on lipid metabolism by showing significant results in reducing the total cholesterol, with more substantial improvements in HDL (good cholesterol) and LDL (bad cholesterol) levels. Ghazvineh et al meta-analysis, showed that yoga had a striking effect on balancing lipid profiles and helps in metabolic syndrome. [31]

Siddha group showed significant results in reducing the PSS levels and improving the QoL levels in all four domains Delta significance proved that YoSi Module showed higher significance in both PSS and QoL Khajuria et al review states that yoga proves to

be an effective method for overall stress reduction. [32] Keerthi et al concludes that 12 weeks of yoga when given along with standard treatment improved quality of life and reduced diabetes risk score in prediabetics and diabetics. [21]

In Neikuri analysis, we found that at baseline in YoSi group 45.3% are vathakapham, 17% pithakapham 13.2% kaphapitham and in Siddha group 43.1% vathakapham, 21.16% pithakapham, 13.7% kaphavatham showing the disturbance of kapha kutram and after intervention majority fall under pitham in YoSi 86.8% and in Siddha group 64.7% which shows that after intervention the neikuri patterns reached single humor state which indicated a good prognosis as stated by Jeyavenkatesh et al (2022) study. [33]

Initially in Neikuri analysis, majority of the subjects spreading nature of oil on urine were fast, irregular and different pattern of spread in both the groups (YoSi 81.2%; Siddha 74.5%) which changed into slow, regular spread (YoSi 100%;Siddha 98%). Shape of spread in both the groups was not circular, Salladaikkan, no spread (YoSi 75.5%; Siddha 82.4%) which was changed into circular shape (YoSi 100%; Siddha 96.1%) after intervention. Both groups have no uniform spread of oil initially (YoSi 81.1% Siddha 86.3%) which changed into uniform shape (YoSi 100%; Siddha 96.1%) after intervention, these changes (slow regular, circular, uniform) after intervention indicate good prognosis.[34] In Neikuri analysis both YoSi and siddha group showed good prognosis which was also seen in all measured parameters.

The findings of this study highlight the effectiveness of the YoSi Module in improving metabolic, physiological, and psychological parameters in T2DM. The significant reductions in weight, BMI, WC, blood pressure, FBS, PPBS, HbA1c, and insulin resistance indicate enhanced glycemic control and metabolic stability, aligning with previous studies. Improvements in lipid profile status, PSS, and QoL further emphasize the holistic benefits of these interventions. Neikuri analysis (which is a unique tool has been included and assessed in this study, is a novel feature which is not found in other research studies) revealed a shift towards single-humor dominance and a more uniform spread, indicating a positive prognostic impact. Overall, these results suggest that the integration of YoSi Module offers a comprehensive approach to diabetes management, supporting both metabolic health and psychological well-being.

8. Conclusions

Integration of traditional therapeutic modalities such as Yoga and Siddha has resulted in beneficial impact in the management of T2DM. It was found in our study that YoSi has effectively regulated the glycemic indices apart from reducing insulin resistance. Appropriate improvements have been found in the lipid profile values. Significant reduction of perceived stress along with enhanced overall quality of life in all the domains has been established in our study participants. All the above findings has also been confirmed by Neikuri analysis which shows good prognosis.

In conclusion, the holistic approach of YoSi module has been proven to be a comprehensive, non-invasive and cost-effective therapeutic modality in managing T2DM. This module could play a pivotal role in improving overall health, quality of life of individuals with T2DM apart from preventing the progression of the disease. Hence it is suggested that YoSi module may be included in the management of diabetes.

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Appendix

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Effect of Integrated Module of Siddha and Yoga on Blood Sugar Level in the management of Type 2 Diabetes

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ABSTRACT: Indian systems of medicine prove effective in management of Diabetes. Siddha medicine and Yoga are holistic traditional Indian systems of medicine which treat the individual as a whole and not the disease.

To study the combined effect of integrated Siddha medicine and Yoga therapy on blood sugar level in the treatment of non-insulin dependent diabetes.

This study is a randomized controlled trial with 109 diabetic subjects attending Siddha OPD, Puducherry, were split up into two groups. Yoga group (Group A) received yoga training for 4 months with standard siddha medication (n = 54) and Control group (Group B) received only standard siddha medication (n =55). Pre and post assessment of glycated hemoglobin (HbA1c), postprandial blood sugar (PPBS) and fasting blood sugar (FBS)were done before and after yoga training respectively.

Baseline values were comparable. FBS was statistically significant in Group A ($p< 0.001$) whereas there was no statistical significance in Group B. PPBS and Hb1Ac were statistically significant in both the groups ($p< 0.001$)

Integrated Siddha and Yoga showed effective reduction in FBS, PPBS and Hb1Ac whereas siddha treatment showed significant reduction in PPBS and Hb1Ac. We may conclude that integrating yoga therapy along with siddha medicine proves potential and effective in treatment of diabetes.

Keywords: Integrated siddha-yoga protocol, fasting blood sugar, post prandial, HbA1c, holistic

INTRODUCTION

Diabetes is a Chronic metabolic condition characterized by high blood sugar levels, which over time produce major harm to the heart, blood vessels, eyes, kidneys and nerves causing global threat and disease burden to the society day by day which initiates new research studies for its prevention, delaying the onset and proper management. Nearly 537 million adults worldwide have diabetes, and that figure is expected to riseup to 643 million by 2030 and 783 million by 2045, according to the International Diabetes Federation (International Diabetes Federation, 2021).

Type 2 diabetic besides hyperglycemia and deranged lipid profile is an impaired insulin secretion, peripheral insulin resistance and obesity which has become a major health concern worldwide. Yoga is a physical and mental discipline that originated in Indian culture over 2,000 years ago (Khosravi *et al*., 2015).

The average yearly direct and indirect expenditures for treating diabetes were calculated to be 25,391 and 4,970 rupees, respectively, in India (Tharkar *et al.,* 2010) and on an average, the medical costs were 2.3 times greater than they would have been without diabetes (American Diabetes Association, 2018). In developing nations, better public healthcare and cost-effective solutions can stop the rising expenses of treating diabetes mellitus. According to studies, yoga is an inexpensive technique that can help to prevent and reduce the health risks related to diabetes (Nagarathna *et al.,* 2020). WHO advises nutritious diet, frequent exercise, and adhering to appropriate weight to avoid or postpone the onset of diabetes which initiates to study the impact of indigenous medical systems on diabetes which emphasis on proper diet, life style modifications and social wellbeing.

The study revealed that the selected blood sugar and blood pressure were significantly reduced due to the influence of yogic practices and naturopathy treatments in diabetic patients (Soni *et al*., 2013).

Yoga therapy is one which is very effective in both the cases i.e. changes in body circulations and heat regulatory disturbance in outer parts (Lodhi *et al*., 2021).

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Validation of *Neikuri*, a Traditional Siddha Diagnostic Technique, and its Influence on HbA1c in Type 2 Diabetic Patients: A Prospective Observational Study

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Siddha medicine, one of the AYUSH systems of medicine was an ancient traditional system with its unique method of diagnosis called Envagai thervu (Eight methods of diagnosis). Among the eight tools Neikuri gained significant importance in diagnostic and prognostic purposes of disease elaborated by Siddhar Theraiyar. To validate the Siddha diagnostic tool, the Neikuri pattern, and to find the correlation with HbA1c levels among type 2 diabetic patients 104 diagnosed diabetic patients consisting of males (n = 56) and females (n = 48) who attended Siddha Clinic were taken for the study. Assessment of Siddha diagnostic tool, Neikuri, was done based on the standardization. HbA1c Blood test was done at our hospital The subject, mean age was 51.86±9.44 years. The pattern of spread on the surface of urine among diabetic patients indicating the derangement of humours in percentage was Vathakapham (44.23%), Pithakapham (19.23%), Kaphapitham (10%), Kaphavatham (8.65%), Kapham (7.69%), Pithavatham (6.73%), Vathapitham(1.92%), and Pithathilpitham (1.92%), We noticed a fast spread (77.88%), Non-circular (78.85%), and non-uniform (83.65%), patterns indicate the vitiation of humors. Different shapes of spread were noted which are indicators of the prevailing disease. Comparison of Neikuri analysis, with HbA1C (glycated haemoglobin) level shows that the subjects having kapham as muthanmai kuttram, the mean HbA1c level was 8.4% and Kapham as thunai kuttram it was 7.95%, whereas when kapham involvement was not present, it was 7.5 %. This shows that HbA1c levels are high when Kapham kuttram is involved, and p-value less than 0.05 when compared with muthanmai kuttram kapham with no kapham proves significance. This convenient, non-invasive, cost-effective technique may prove beneficial in the diagnosis and prognosis of the disease, showing instant results of the actual health condition.

Keywords: diabetes, HbA1c, Kuttram, Kapham, Neikuri, Siddha

The Siddha medicine, one of the medical systems of AYUSH, is an ancient system from South India and was formed by Siddhars through their supreme wisdom and supernatural powers (siddhigal). The Siddha system teaches various disciplines to be practiced in day-to-day life for healthy well-being and its unique for its holistic approach (Shanmugavelu et al., 2009).

Diabetes is a chronic metabolic disorder, which is comparable to the term *Madhumegam* in Siddha medicine (Balamanohary et al., 2018; Muthappan et al., 2020). Saint Yugi elaborates on 21 varieties of Mega noigal in the book *Yugi vaidhiya chintamani* in Siddha

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We have no known conflict of interest to disclose. Correspondence concerning this article should be addressed to Dr. Meena Ramanathan, Vice Principal, I Block, 1st Floor, School of Yoga Therapy, ISCM, Mahatma Gandhi Medical College, SBV Campus, Sri Balaji Vidyapeeth University, Puducherry, Puducherry, E-mail: saineema@gmail.com

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